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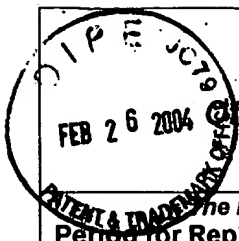
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Application No.

09/160,076

Applicant(s)

SCOTT ET AL.

Examiner

Michael C. Wilson

Art Unit

1632

Office Action Summary

SEP 02 2003

Morrison & Forester, LLP
Palo Alto

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

COPY

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

RS-CD
DOCKETED 10/27/03
REMINDER: 11/28/03
FINAL DUE DATE: 2/28/04

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 79-81 have been added. Claims 69-81 are pending and under consideration in the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's arguments filed 5-30-03, paper number 42, have been fully considered.

Specification

The first line of the specification needs updated to reflect that parent application 08/195874 is now US Patent 5,817,308.

The blanks on pg 16 must be filled in.

The title should be changed to reflect the claims are directed toward cells expressing fusion proteins of immunoglobulins.

Priority

The claim for domestic priority to 08/195874, now US Patent 5,817,308, is acknowledged.

Claim Rejections - 35 USC § 112

The rejection of claim 75 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn because the term "transduction" has been deleted.

Art Unit: 1632

The rejection of claims 69-78 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn.

The rejection of claims 69-78 under 35 U.S.C. 112, first paragraph, scope rejection, has been withdrawn.

1. Claim 70, 72 and 74 remain rejected and claims 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of the phrase “a polypeptide containing... ..to which tolerance is desired to be induced” (claim 69) has been withdrawn because the phrase “to which tolerance is desired to be induced” has been deleted.

Claim 70 is indefinite as newly amended because it is not clear that the nucleic acid sequence in claim 69 was introduced into the cell. The phrase “wherein said nucleic acid sequence is a viral vector” would overcome this rejection.

Claim 72 is indefinite as newly amended because claim 69 is not directed toward a fusion protein and because the claim is dependent on two claims for two different things. Overall, the structure of the limitation is unclear. The phrase “wherein there are two or more copies of said nucleic acid sequence” would overcome this rejection.

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The rejection of claim 74 has been withdrawn because the phrase "or portion thereof" has been deleted.

The phrase "the first framework region of said N-terminal variable region" (claim 74) lacks antecedent basis in parent claims 69 or 70. It is not clear "the first framework region" must occur in the "N-terminal variable region" in parent claims 70 or 69. What is a "framework region"?

The term "autoimmune antigen" (claim 80) is indefinite for reasons of record regarding autoantigen.

Claim 81 is indefinite. The term "allergan" cannot be found in the art. The term is not defined in the dictionary or in the specification.

Claim Rejections - 35 USC § 102

The rejection of claim 69 under 35 U.S.C. 102(e) as being anticipated by Zanetti of record (US Patent 5,508,386, April 16, 1996) has been withdrawn because the claim now requires a non-tumor hematopoietic cell.

The rejection of claim 69 under 35 U.S.C. 102(b) as being anticipated by Zambidis of record (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) has been withdrawn because the claim now requires a non-tumor hematopoietic cell.

The following is a new rejection under 102:

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2. Claims 69 and 76-81 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonnell et al. (Cell, 1989, Vol. 57, pg 79-88).

McDonnell taught a transgenic mice whose genome comprised a transgene comprising bcl-2-Ig fusion protein. Splenocytes and thymocytes were isolated from the mice in saline and media. The splenocytes and thymocytes are non-tumor lymphoid cells and are equivalent to the composition claimed because they have the structure claimed. The bcl-2-Ig fusion protein is equivalent to the fusion protein required in the claim because it has a heavy chain immunoglobulin and bcl-2. The bcl-2 protein inherently has at least one epitope as claimed. The cells of McDonnell inherently "induces tolerance to an antigen" because it has the same structure as the cell claimed. The phrase "for introduction into an individual" does not bear patentable weight because they are intended uses and may not occur. These intended uses do not bear patentable weight because they do not alter the structure of the composition. The composition of McDonnell inherently meets the functional limitation of "wherein upon introduction to the individual said composition induces tolerance to the antigen in the individual" because it has the structure claimed. [The cells are syngeneic to mice of other strains (claim 76). The splenocytes and thymocytes are "bone marrow cells" (claim 77) because they originated in the bone marrow. The splenocytes and thymocytes inherently have "B-cells" (claim 78) because B-cells are found in the spleen and thymus.] The splenocytes and thymocytes inherently comprise "hematopoietic cells" (claim 81) because they comprise pluripotent cells capable of differentiation. Claims 82

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and 83 are included because the metes and bounds of the limitations cannot be determined (see 112/2nd); therefore, bcl-2 is an autoimmunogen and an allergan.

Claim Rejections - 35 USC § 103

The rejection of claims 69-78 35 U.S.C. 103(a) as being unpatentable over Chambers (Feb. 1992, PNAS, USA, Vol. 89, pages 1026-1030) in view of Zambidis (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) has been withdrawn. Zambidis taught a tumor cell for producing a fusion immunoglobulin *in vitro* while chambers taught cells for inducing an immune response use *in vivo*. Therefore, the one of ordinary skill in the art would not have been motivated to combine Chambers and Zambidis.

Double Patenting

3. Claim 75 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 70. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims require the nucleic acid is introduced into the cell via a viral vector.

Conclusion

No claim is allowed.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

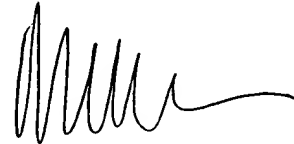
Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line.

**MICHAEL WILSON
PRIMARY EXAMINER**

Notice of References Cited	Application/Control No. 09/160,076	Applicant(s)/Patent Under Reexamination SCOTT ET AL.	
	Examiner Michael C. Wilson	Art Unit 1632	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	McDonnell et al. Cell, April 7, 1989, Vol. 57. pg 79-88.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/160,076	09/24/1998	DAVID WEST	308072000110	5918

25226 7590 08/28/2003

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Palo Alto

EXAMINER

WILSON, MICHAEL C

ART UNIT PAPER NUMBER

1632

44

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

COPY



Inventor: David W. SCOTT and Elias T. ZAMBIDIS

Atty Docket No.: 308072000110

Application No.: 09/160,076

Filing Date: September 24, 1998

Title: TOLEROGENIC FUSION PROTEINS OF IMMUNOGLOBULINS AND
METHODS FOR INDUCING AND MAINTAINING TOLERANCE

Documents Filed:

Transmittal (1 page)

Amendment (18 pages)

Copy of ATCC deposit slip (1 page)

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Palo Alto



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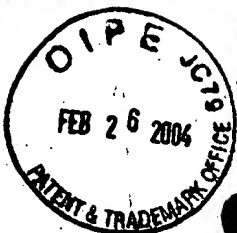
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REVISED AMENDMENT PRACTICE: 37 CFR 1.121 CHANGED
COMPLIANCE IS MANDATORY - Effective Date: July 30, 2003

Amendments filed on or after the effective date noted above must comply with revised 37 CFR 1.121. See Final Rule: *Changes To Implement Electronic Maintenance of Official Patent Application Records* (68 Fed. Reg. 611 (June 30, 2003)), posted on the Office's website at: <http://www.uspto.gov/web/patents/ifw/> for related information. The amendment practice set forth in revised 37 CFR 1.121, and described below, replaces the voluntary revised amendment format available to applicants since February 2003. **NOTE: STRICT COMPLIANCE WITH THE REVISED 37 CFR 1.121 IS REQUIRED AS OF THE EFFECTIVE DATE (July 30, 2003).** The Office will notify applicants of amendments that are not accepted because they do not comply with revised 37 CFR 1.121 via a Notice of Non-Compliant Amendment. See MPEP 714.03 (Rev. 1, Feb. 2003). The non-compliant section(s) will have to be corrected and the entire corrected section(s) resubmitted within a set period.

Old underlined italic font has been used below to highlight the major differences between the revised 37 CFR 1.121 and the voluntary revised amendment format that applicants could use since February, 2003.
Note: The amendment practice for reissues and reexamination proceedings, except for drawings, has not changed.

REVISED AMENDMENT PRACTICE

Begin each section of an amendment document on a separate sheet:
Each section of an amendment document (e.g., Specification Amendments, Claim Amendments, Drawing Amendments, and Remarks) must begin on a separate sheet. Starting each separate section on a new page will facilitate the process of separately indexing and scanning each section of an amendment document for placement in an image file wrapper.

Two versions of amended part(s) no longer required:
37 CFR 1.121 has been revised to **no longer require** two versions (a clean version and a marked up version) of each replacement paragraph or section, or amended claim. Note, however, the requirements for a clean version and a marked up version for **substitute specifications** under 37 CFR 1.125 have been retained.

Amendments to the claims:
Each amendment document that includes a change to an existing claim, cancellation of a claim or submission of a new claim, must include a complete listing of all claims in the application. After each claim number in the listing, the status must be indicated in a parenthetical expression, and the text of each pending claim (with markings to show **current changes**) must be presented. The claims in the listing will replace all prior claims in the application.

- (1) The current status of all of the claims in the application, including any previously canceled, not entered or withdrawn claims, must be given in a parenthetical expression following the claim number using only one of the following seven status identifiers: (original), (currently amended), (canceled), (withdrawn), (new), **(previously presented)** and **(not entered)**. The text of all pending claims, **including withdrawn claims**, must be submitted each time any claim is amended. Canceled **and not entered** claims must be indicated by only the claim number and status, without presenting the text of the claims.
- (2) The text of all claims **being currently amended** must be presented in the claim listing with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim must be shown by underlining (for added matter) or strikethrough (for deleted matter) with 2 exceptions: (1) for **deletion of five characters or fewer, double brackets may be used (e.g., [[error]]**; and (2) **if strikethrough cannot be easily perceived (e.g., deletion of the number "4" or certain punctuation marks), double brackets must be used (e.g., [[4]])**. As an alternative to using double brackets, however, **extra portions of text may be included before and after text being deleted, all in strikethrough, followed by including and underlining the extra text with the desired change (e.g., number 4 as number 14 as)**. An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended," and "withdrawn" that are being amended, may include markings.
- (3) The text of pending claims **not being currently amended, including withdrawn claims**, must be presented in the claim listing in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version except to omit markings that may have been present in the immediate prior version of the claims.